

REMARKS

Pending Claims

Claims 1–65 are pending in this application. Claims 1–28 were previously cancelled. Claims 29, 32–35, 38–40, 42, 47–51, 53, 56–59, and 62–64 are currently amended. Claims 30–31, 36–37, 41, 43–46, 52, 54–55, and 60–61 were previously presented. Claim 65 is new.

Restriction Required Election

Applicants elect Group 2, encompassing amended claims 29–36 for prosecution on the merits. These claims are directed to fragments of a polypeptide having at least 65% sequence identity with SEQ ID NO: 14 (human collagen IX alpha1 NC4 domain).

This election is made with traverse, as the Examiner has incorrectly applied a U.S. Restriction standard rather than the required Unity of Invention standard required by PCT Rule 13.1 and 13.2.

Unity of Invention Standard is Required

During examination of a national stage application filed under 35 U.S.C. § 371, PCT Rules 13.1 and 13.2 **must** be followed when considering unity of invention of claims of different categories, without regard to the practice in national applications filed under 35 U.S.C. § 111. See MPEP § 1850 citing *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 650 F. Supp. 218 (E.D. Va. 1986).

Applicants submit Groups 1–74 are linked by the same or corresponding special technical feature that forms a single inventive concept. A "special technical feature" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

One special technical feature that unifies the subject matter of the claims is the anti-inflammatory, tolerance-inducing activity exhibited by peptide fragments of the collagen type IX (CIX) alpha chain 1 NC4 domain against stimulation by collagen antigens. Applicants teach

such anti-inflammatory, tolerance-inducing polypeptide fragments of the CIX NC4 domain, their sequences and relative identities, and demonstrate that when these polypeptide fragments are administered either before or after antigenic collagen stimulation, they effectively induce tolerance, stimulate collagen production, and prevent/treat inflammatory and immune response to antigenic stimulation by collagen. Such administration prevents or treats degenerative diseases or disorders such as arthritis and musculoskeletal degenerative conditions. By disclosing this specific activity of the CIX NC4 polypeptide fragments, Applicants teach the range of treatments achieved by the polypeptide fragments. Applicants also teach the sequences of the human, bovine, mouse, and chicken NC4 domains, and the conserved structure of the NC4 polypeptide fragments (see, for example, the attached alignment of the sequences and fragments; See also the Sequence ID listing of record).

Applicants therefore submit the CIX NC4 polypeptide fragments exhibiting collagen tolerance and anti-inflammatory activities discussed above is one special technical feature of the claims that links Groups 1-74 (claims 1-65) so as to form a single inventive concept. Each of the claims requires all the elements of claim 29, and each is linked as product having these technical features and process applying these technical features of the product. The Office Action has not provided any evidence that supports lack of unity of invention or demonstrates that the claims are not linked by a special technical feature.

Furthermore, Applicants disagree with the Examiner's contention that the inventions of Groups 1-74 are unrelated. The claimed polypeptide fragments are each active fragments of the collagen IX $\alpha 1$ NC4 domain. As shown in the attached alignment, four species (human, bovine, murine, and chicken) show significant sequence identity, and the polypeptide fragments 2-11 are highly conserved (See the attached alignment).

As discussed above, Groups 1-14 reciting compositions and Groups 15-31 and 33-71 reciting methods are related as product and process of use. Each of the claims incorporates all the limitations of claim 29 (the generic product claim), and each shares at least one common technical feature, the CIX NC4 polypeptide fragments having immune tolerance and anti-inflammatory, tolerance-inducing activity.

At least because the Examiner has applied an incorrect standard in issuing the Restriction Requirement, and because the correct application of PCT Rule 13.1 and 13.2 Unity of Invention must be applied, withdrawal of this Restriction Requirement and consideration of all the claims under the required Unity of Invention standard is required.

CONCLUSION

In view of the above amendments and remarks, Applicant respectfully requests examination of all of the claims on the merits. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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